IN THE UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF PENNSYLVANIA

LAMONT SINGLETON and JOCELYN WILSON, Administrators of the Estate of ALIVIA SINGLETON, deceased,	)	
Plaintiffs,	)	Civil Action No.:
v.	)	
PHARMATECH LLC and THE HARVARD DRUG GROUP LLC d/b/a RUGBY LABORATORIES	)	**JURY TRIAL DEMANDED**
Defendants.	)	

COMPLAINT IN CIVIL ACTION

Plaintiffs file this Complaint for Damages for injuries resulting from a defective product manufactured, marketed, and sold by Defendants. In support of Plaintiffs' Complaint, Plaintiffs would respectfully show the Court as follows:

I. INTRODUCTION

1. This is a lawsuit regarding injuries arising out of the manufacture, sale and use of defective and dangerous liquid docusate stool softener which was at all relevant times hereto contaminated with Burkholderia cepacia (hereinafter "B. cepacia"), a rare complex of bacteria.

2. The liquid docusate at issue is hereinafter referred to as "docusate", "Diocto Liquid" or the "Product".

3. The Product at issue was manufactured and sold by Defendant PharmaTech, LLC ("PharmaTech") and distributed, labeled and sold by Defendant The Harvard Drug Group, LLC

d/b/a Rugby Laboratories ("Rugby") under the brand name, "Diocto Liquid" in, inter alia, one pint (473 mL) bottles (collectively referred to as "Defendants").

4. Alivia Singleton (hereinafter "Baby Singleton" or "Decedent"), daughter of Plaintiffs, Lamont Singleton and Jocelyn Wilson, and twin sister of Ariana Singleton, was born on August 3, 2015, and died, less than a year later, on May 4, 2016 secondary to a B. cepacia infection she contracted from being administered the Product.

II. PARTIES

5. Lamont Singleton and Jocelyn Wilson, Plaintiffs herein, are the Administrators of the Estate of Alivia James Singleton, deceased having been so appointed by the Register of Wills for the County of Allegheny, in the Commonwealth of Pennsylvania, on June 12, 2017. See copy of the Certificate of Grant of Letters of Administration attached hereto as Exhibit "A.

6. Lamont Singleton and Jocelyn Wilson are the parents of Decedent and are adult residents of Allegheny County, Pennsylvania.

7. Defendant, PharmaTech, LLC, is a Florida limited liability company with its principal place of business at 4131 SW 47th Avenue, Suite 1403, Davie, Florida 33314.

8. Defendant, The Harvard Drug Group, LLC d/b/a Rugby Laboratories, is a Michigan limited liability company with its principal place of business at 31778 Enterprise Drive, Livonia, Michigan 48150. On October 29, 2012, The Harvard Drug Group LLC acquired the Rugby Laboratories from Watson Pharmaceuticals Inc. for approximately $117 million. Thereafter, and at all relevant times hereto, the Rugby's products have been owned and controlled by The Harvard Drug Group LLC.

III. JURISDICTION and VENUE

9. This Court has jurisdiction over this matter pursuant to 28 U.S.C. § 1332(a) as there is complete diversity between the parties.

10. Defendants have submitted to the jurisdiction of this Honorable Court by doing, personally or through agents, at all times material to this lawsuit, the following acts:

a. Committing tortious acts within this state by selling and delivering defective products, including the Product, to persons, firms, corporations, pharmacies or hospitals in this state via its distributors, dealers, wholesalers, retailers and/or brokers. Such products were used by consumers in Pennsylvania in the ordinary course of trade, commerce or healthcare;

b. Conducting and engaging in substantial business and other activities in Pennsylvania by selling its products to persons, firms, corporations, pharmacies or hospitals in this state via its distributors, dealers, wholesalers, retailers and/or brokers;

c. Causing injuries to persons in Pennsylvania, including Baby Singleton, and likely others. At or about the time of said injuries, Rugby engaged in solicitation activities in Pennsylvania to promote the sale of its products;

d. Selling defective products, including the Product, with knowledge or reason to foresee that its product would be shipped in interstate commerce and would reach the market of Pennsylvania users or consumers.

11. Venue lies in the Western District of Pennsylvania because the unlawful actions giving rise to this complaint, and the injuries suffered, occurred within the district.

IV. FACTS

12. Baby Singleton, daughter of Plaintiffs, Lamont Singleton and Jocelyn Wilson, and twin sister of Ariana Singleton, was born on August 3, 2015, and required hospitalization at the University of Pittsburgh Medical Center's ("UPMC") Children's Hospital in January 2016 until the time of her death on May 4, 2016 for chronic lung disease secondary to reflux aspiration.

13. Beginning in January 2016 and throughout the course of her aforesaid hospitalization, Baby Singleton was regularly administered the Product, which had been labeled and sold to UPMC by Rugby, and which was part of lot NDC 0536-0590-85.

14. In February 2016, Baby Singleton was diagnosed as suffering from a pulmonary-based B. cepacia infection.

15. B. cepacia is a gram-negative bacillus found in various aquatic environments and opportunistic human pathogen that often causes life-threatening pneumonia in immunocompromised individuals with underlying lung disease.

16. In June of 2016, the Centers for Disease Control and Prevention ("CDC") reported that it was investigating in collaboration with the Food and Drug Administration ("FDA"), a multi-state outbreak of B. cepacia infections.

17. In mid-July of 2016, PharmaTech, voluntarily and publicly recalled all non-expired lots of its Diocto Liquid, distributed by Rugby.

18. The FDA confirmed the Product was contaminated with B. cepacia, and linked to an outbreak in five states, including Pennsylvania.

19. As part of its recall, PharmaTech stated publicly, "Use of docusate sodium liquid contaminated with B. cepacia may result in serious infections that could be life-threatening in patients with compromised immune systems and in patients with chronic lung conditions such as cystic fibrosis."

20. PharmaTech also stated publicly, "All lots with NDC 0536-0590-85 are included in the recall. Diocto Liquid was distributed nationwide to wholesale and retail facilities including hospitals and pharmacies."

21. By October 2016, an FDA investigation into the aforesaid outbreak and recall, had identified the presence of B. cepacia in multiple lots of liquid docusate, including NDC 0536-0590-85, manufactured by PharmaTech, and traced the source of the B. cepacia to the water system used by PharmaTech to manufacture the Product.

22. The CDC reported that laboratory evidence from the FDA and CDC supported PharmaTech as the source of the B. Cepacia outbreak.

23. As part of a detailed investigation into the root cause of the defective Product, the FDA's inspectors found several deviations from good manufacturing practices at PharmaTech's Florida manufacturing facility. These included the failure to monitor water quality and to establish and follow procedures that are "designed to prevent objectionable microorganisms in drug products not required to be sterile."

24. Inspectors also found that PharmaTech did not appropriately test each batch of finished Product for the presence of objectionable organisms like B. Cepacia.

25. According to a report issued by the FDA, there was more than one instance in which PharmaTech failed to investigate customer reports of contaminants or to determine the root cause of PharmaTech's own findings of microbial contamination.

26. The Product Baby Singleton was administered throughout her hospitalization was lot NDC 0536-0590-85, which was contaminated with B. Cepacia.

27. Baby Singleton, and likely others similar to her, ultimately died as a result of her B. cepacia infection which she contracted from the contaminated Product administered to her throughout her aforesaid hospitalization.

28. At all relevant times, the Defendants' actions as described herein were reckless, wanton and/or done in conscious disregard of the safety of others including Baby Singleton.

V. CAUSES OF ACTION

COUNT I – WRONGFUL DEATH

STRICT LIABILITY - § 402A RESTATMENT (SECOND) OF TORTS

LAMONT SINGLETON and JOCELYN WILSON, Administrators of the Estate of ALIVIA SINGLETON, deceased v. PHARMATECH LLC, THE HARVARD DRUG GROUP LLC d/b/a RUGBY LABORATORIES

29. Plaintiffs hereby incorporate by reference all preceding paragraphs of this Complaint as if fully set forth herein.

30. At all times relevant hereto, PharmaTech was in the business, *inter alia*, of selling pharmaceuticals, *inter alia*, the Product.

31. PharmaTech designed, tested, validated, manufactured, fabricated, and/or assembled the Product in an unreasonably dangerous and defective manner.

32. PharmaTech and/or Rugby marketed, distributed, sold, and/or supplied the Product in a dangerously defective condition.

33. The Product was sold and delivered to Baby Singleton's medical providers in the same dangerously defective condition, without substantial change, in which it left Defendants' possession and/or control.

34. Decedent's injuries including her death were caused by and resulted from the acts and/or omissions of Defendants independently and/or jointly, by and through their agents, servants, workman, subagents, employees, and/or representatives acting in the course and scope of their employment, for which the Defendants are strictly liable pursuant to §402A of the Restatement (Second) of Torts in:

a. Designing, manufacturing, fabricating, compounding, marketing, distributing, selling and/or creating a dangerously defective Product which subjected Decedent to an unreasonable risk of harm;

b. Failing to adequately and properly, test, validate, and/or inspect the subject Product to discover defects in it, thereby creating an unreasonable risk of harm to Decedent;

c. Failing to provide adequate and sufficient warning of the dangerously defective condition of the Product, which created an unreasonable risk of harm to Decedent;

d. Failing to properly and adequately warn Decedent and/or Decedent's Doctors and Medical Providers, who Defendants should have known would make use of the unreasonably dangerous and defective Product, thereby subjecting Decedent to an unreasonable risk of harm;

e. Failing to test each batch of finished Product for the presence of objectionable organisms like B. Cepacia and thus causing the dissemination of the Product in an adulterated condition that posed an unreasonable risk of harm to end users, including Decedent;

f. Failing to monitor water quality and/or to establish and follow procedures that designed to prevent objectionable microorganisms in drug products not required to be sterile," and thus causing the dissemination of the Product in an adulterated condition that posed an unreasonable risk of harm to end users, including Decedent;

35. As a direct and proximate result of the Defendants' acts and/or omissions for which Defendants are strictly liable pursuant to § 402A of the Restatement Second of Torts, the Product caused both Decedent's exposure to B. cepacia, subsequent B. cepacia infection and death caused thereby.

36. As a direct and proximate result of the Defendants' strict liability which caused the aforesaid exposure and subsequent infection, Baby Singleton suffered grave injuries which were serious and permanent in nature, including but not limited to, B. cepacia infection, pneumonia, respiratory distress, shock, multiple organ failure, and death.

37. As a direct and proximate result of the Defendants' strict liability which caused the aforesaid exposure and subsequent infection, Baby Singleton required extensive medical treatment and life-sustaining efforts brought to an end only by her death.

38. As a direct and proximate result of the Defendants' strict liability which caused the aforesaid exposure and subsequent infection, Baby Singleton suffered severe physical pain and trauma, mental upset and anguish, and experienced same up and until the time of her death.

39. As a direct and proximate result of the Defendants' strict liability which caused the aforesaid exposure and subsequent infection, Baby Singleton suffered a diminution in her ability to enjoy life and life's pleasures, all of which continued until the time of her death.

40. Decedent was nine (9) months young at the time of her death and left surviving two adult parents and a twin sister:

a. Lamont Singleton (Father)
2936 East Hardies Road
Gibsonia, PA 15044

b. Jocelyn Wilson (Mother)
2936 East Hardies Road
Gibsonia, PA 15044

c. Ariana Singleton (Sister)
2936 East Hardies Road
Gibsonia, PA 15044

41. Plaintiffs bring this action pursuant to 42 Pa. C. S. §8301 and Pa. R.C.P. No. 2202 to recover all damages which the Plaintiffs and all wrongful death heirs of the decedent are entitled to recover under the laws of Pennsylvania for the wrongful death of Baby Singleton.

42. Decedent did not bring an action for her personal injuries during her lifetime.

WHEREFORE, Plaintiffs demand judgment in their favor and against Defendants PharmaTech, LLLC, and The Harvard Drug Group, LLC d/b/a Rugby Laboratories for all damages recoverable under the law of this Commonwealth in an amount in excess of this jurisdictions board of arbitrators plus interest, costs, and any other amount that this Honorable Court deems fit to award.

COUNT II: WRONGFUL DEATH
STRICT LIABILITY - § 402B RESTATMENT (SECOND) OF TORTS
LAMONT SINGLETON and JOCELYN WILSON, Administrators of the Estate of ALIVIA SINGLETON, deceased v. PHARMATECH LLC, THE HARVARD DRUG GROUP LLC d/b/a RUGBY LABORATORIES

43. Plaintiffs hereby incorporate by reference all preceding paragraphs of this Complaint as if fully set forth herein.

44. At all times relevant hereto, Defendants was in the business, *inter alia*, of selling medical devices, *inter alia*, Product.

45. Defendants marketed, advertised, labeled and/or otherwise made public misrepresentation(s) of material fact related and/or pertaining to the safety and/or efficacy of the Product.

46. Decedent's medical providers purchased and used the Product justifiably relied upon the above detailed misrepresentations when purchasing and using the Defendants' Product.

47. Decedent's injuries were caused by and resulted from the acts, omissions and/or misrepresentations of Defendants, by and through their agents, servants, workman, subagents, employees, and/or representatives acting in the course and scope of their employment, for which Defendants' is strictly liable pursuant to §402B of the Restatement (Second) of Torts.

48. As a direct and proximate result of Defendants' acts and/or omissions for which Defendants are strictly liable pursuant to §402B of the Restatement Second of Torts, the defective Product caused both Decedent's exposure and subsequent infection and death.

49. As a direct and proximate result of Defendants' strict liability which caused the aforesaid exposure and subsequent infection, Baby Singleton suffered grave injuries which were serious and permanent in nature, including but not limited to, B. cepacia infection, pneumonia, respiratory distress, shock, multiple organ failure, and death.

50. As a direct and proximate result of Defendants' strict liability which caused the aforesaid exposure and subsequent infection, Baby Singleton required extensive medical treatment and life-sustaining efforts all of which continued until the date of her death.

51. As a direct and proximate result of Defendants' strict liability which caused the aforesaid exposure and subsequent infection, Baby Singleton suffered severe physical pain and trauma, mental upset and anguish and continued to suffer the same until she died.

52. As a direct and proximate result of Defendants' strict liability which caused the aforesaid exposure and subsequent infection, Baby Singleton suffered a diminution in her ability to enjoy life and life's pleasures, all of which she suffered continuously until the date of her death.

WHEREFORE, Plaintiffs demand judgment in their favor and against Defendants PharmaTech, LLLC, and The Harvard Drug Group, LLC d/b/a Rugby Laboratories for all damages recoverable under the law of this Commonwealth in an amount in excess of this jurisdictions board of arbitrators plus interest, costs, and any other amount that this Honorable Court deems fit to award.

COUNT III: WRONGFUL DEATH NEGLIGENCE

LAMONT SINGLETON and JOCELYN WILSON, Administrators of the Estate of ALIVIA SINGLETON, deceased v. PHARMATECH LLC, THE HARVARD DRUG GROUP LLC d/b/a RUGBY LABORATORIES

53. Plaintiffs hereby incorporate by reference all preceding paragraphs of this Complaint as if fully set forth herein.

54. Defendants had a duty to exercise reasonable care in the design, manufacture, testing, validating, labeling, marketing, advertising and distribution into the stream of commerce of the Product, including a duty to ensure that the Product did not pose a significantly increased risk of infection, death or other adverse events.

55. Defendants breached the above detailed duty in that they failed to exercise reasonable care, *inter alia*, in the design, manufacture, testing, validating, labeling, marketing and distribution into the stream of commerce of the Product.

56. Defendants' negligence included, but is not limited to, the following:

a. Failing to properly monitor the quality of water used to manufacture the Product so as to prevent contamination by objectionable microorganisms;

b. Failing to ensure that the water used to manufacture the Product was free of objectionable organisms like B. cepacia;

c. Failing to establish and/or follow policies, procedures and/or standards in the manufacture of the Product designed to prevent objectionable microorganisms in drug products not required to be sterile.

d. Failing to design, manufacture, test, validate, label, market and/or distribute a safe and effective Product in that the Product was contaminated with B. cepacia, which Defendants knew or should have known posed an unreasonable risk of injury or death to end users, including Decedent;

e. Failing to properly test, validate and/or investigate the quality and safety of the Product prior to marketing and sale of same to make sure it was not contaminated with B. cepacia ;

f. Failing to protect Decedent from known and/or knowable risks associated with the Product in its adulterated form;

g. Failing to properly design, implement and enforce sufficient post-manufacture or post-market monitoring of the Product so as to prevent the Product, in its adulterated form, from reaching end users, like Decedent;

h. Failing to stay informed of and up to date with the existing scientific literature related to the safe and proper design, manufacture, testing, validation, labeling, marketing and/or distribution of the Product;

i. Failing to investigate customer reports and complaints of contaminants in the Product prior to the Product reaching end users, including Plaintiff, in its adulterated form;

j. Failing to take any meaningful steps to determine the root cause of Defendants' own findings of microbial contamination in the Product;

k. Failing to timely act when Defendant knew or should have known that the Product had been distributed to end users in an adulterated form;

l. Failing to disclose important material facts related and/or pertaining to the safety of the Product to Decedent and/or Decedent's medical providers and physicians;

m. Failing to disclose that the Product was not safe for use as designed and/or intended when Defendants knew or should have known thereof;

n. Defendants failed to disclose that the reprocessing instructions for the Product were inadequate;

o. Failing to disclose or warn that the Product was not safe for use on patients with chronic pulmonary disease or compromised immune systems;

p. Any other instances of negligence to be determined through the discovery process; and

q. Any other instances of negligence under the common law and/or applicable statutes, codes and/or regulations.

57. At all times relevant hereto, the Product was defective, Defendants knew or should have known that it was defective and that the Product was to be used recurrently by the medical service provider end user, without further inspection for defects in the Product, upon patients, like Decedent.

58. Defendants knew or should have known of the dangers associated with the Product.

59. Despite the fact that Defendants knew or should have known that the Product was dangerous and defective, Defendants continued to manufacture, assemble, advertise, market, promote, supply, distribute, and/or sell the Product as a safe and effective pharmaceutical medication.

60. In so doing, the Defendants failed to act as a reasonable manufacturer, seller and/or distributer of the Product.

61. Defendants took these actions in conscious disregard of the foreseeable harm and of the rights and safety of consumers caused by the unapproved and defective Product.

62. Neither Decedent nor Plaintiffs knew, nor had reason to know, at the time of the use of the subject Product, of the existence of the aforementioned defects, nor could they have discovered the defects in the Product through the exercise of reasonable care.

63. At the time the Product was introduced into the Decedent's body through repeated medication administrations, it had not been materially altered or modified, since its manufacturing, labeling and packaging by the Defendants, prior to its use in Decedent.

64. As a direct and proximate result of Defendants' negligence Decedent was caused to be exposed and to contract a B. cepacia infection and die as a result thereof.

65. As a direct and proximate result of Defendants' negligence which caused the aforesaid exposure and subsequent infection, Baby Singleton suffered grave, serious and ongoing injuries which culminated in her death and which are more fully and completely set forth above and incorporated herein.

WHEREFORE, Plaintiffs demand judgment in their favor and against Defendants PharmaTech, LLLC, and The Harvard Drug Group, LLC d/b/a Rugby Laboratories for all damages

recoverable under the law of this Commonwealth in an amount in excess of this jurisdictions board of arbitrators plus interest, costs, and any other amount that this Honorable Court deems fit to award.

COUNT IV: WRONGFUL DEATH
BREACH OF WARRANTY

LAMONT SINGLETON and JOCELYN WILSON, Administrators of the Estate of ALIVIA SINGLETON, deceased v. PHARMATECH LLC, THE HARVARD DRUG GROUP LLC d/b/a RUGBY LABORATORIES

66. Plaintiffs incorporate by reference all preceding paragraphs of this Complaint as if fully set forth herein.

67. In designing, manufacturing, fabricating, assembling, distributing, supplying, labeling and selling the subject Product, Defendants knew and intended that said product would be used by members of the public, such as the Decedent.

68. Decedent, Plaintiffs and/or Decedent's medical providers had a right to, and did rely upon, the superior skill, experience, expertise and knowledge of Defendants in designing, manufacturing, fabricating, labeling and assembling the Product.

69. Plaintiffs believe, and therefore aver, that Defendants, by the virtue of their sales operations, advertisements, promotional literature and brochures, made certain express warranties that the subject Product was free from defects and safe for use as directed and as occurred in Decedent.

70. By distributing the Product into the stream of commerce, Defendants further warranted that the subject Product was reasonably fit for the purpose and use intended and was of merchantable quality, when in fact, it was not reasonably fit for the purpose and use intended and was not of merchantable quality.

71. Defendants breached their express warranties and the implied warranties of merchantability and fitness for the particular purpose and use intended in the manner set forth above.

72. Defendants' breach of said express and implied warranties was a direct and proximate cause of the injuries sustained by Decedent as set forth herein.

73. As a direct and proximate result of Defendants' acts and/or omissions, Defendants is liable for breach of warranty that caused both Decedent's exposure, subsequent infection and death.

74. As a direct and proximate result of Defendants' breach of warranty which caused the aforesaid exposure and subsequent infection, Baby Singleton suffered grave, serious and ongoing injuries which culminated in her death and which are more fully and completely set forth above and incorporated herein.

WHEREFORE, Plaintiffs demand judgment in their favor and against Defendants PharmaTech, LLLC, and The Harvard Drug Group, LLC d/b/a Rugby Laboratories for all damages recoverable under the law of this Commonwealth in an amount in excess of this jurisdictions board of arbitrators plus interest, costs, and any other amount that this Honorable Court deems fit to award.

COUNT V: SURVIVAL

LAMONT SINGLETON and JOCELYN WILSON, Administrators of the Estate of ALIVIA SINGLETON, deceased v. PHARMATECH LLC, THE HARVARD DRUG GROUP LLC d/b/a RUGBY LABORATORIES

75. Plaintiffs incorporate by reference all preceding paragraphs of this Complaint as if fully set forth herein.

76. Plaintiffs bring this action on behalf of the Estate of Alivia Singleton, deceased, under and by the virtue of the laws of the Commonwealth of Pennsylvania and other applicable statutes, including 20 Pa. C.S.A. §3373 and 42 Pa. C.S.A. §8302 to recover all damages of whatsoever nature to which said Estate is entitled by reason of the death of Decedent under the laws governing survival act.

77. As a direct and proximate result of the strict liability and negligence of Defendants as aforesaid, Decedent suffered great pain, suffering, inconvenience, and loss of enjoyment of her life as described herein. She was confined to a hospital for the latter portion of her life. Her health in general was seriously and permanently impaired for the remainder of her life.

78. As a further direct and proximate result of the strict liability and negligence of Defendants as aforesaid, Decedent was required to have large sums of money expended upon her behalf for doctors, hospitals and other items necessary for her care.

79. Plaintiffs claim on behalf of the said estate the damages suffered by the estate by reason of the death of Minor Decedent, including the loss of future earnings, expenses of administration and the pain and suffering of decedent prior to her death.

WHEREFORE, Plaintiffs demand judgment in their favor and against Defendants PharmaTech, LLLC, and The Harvard Drug Group, LLC d/b/a Rugby Laboratories for all damages recoverable under the law of this Commonwealth in an amount in excess of this jurisdictions board of arbitrators plus interest, costs, and any other amount that this Honorable Court deems fit to award.

JURY TRIAL DEMANDED

Respectfully submitted,

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